



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,046	11/20/2001	Frederic J. de Sauvage	P1405R1C1	1433
9157	7590	11/09/2009		
GENENTECH, INC. 1 DNA WAY SOUTH SAN FRANCISCO, CA 94080			EXAMINER HOWARD, ZACHARY C	
			ART UNIT 1646	PAPER NUMBER
			MAIL DATE 11/09/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/990,046

Applicant(s)

DE SAUVAGE ET AL.

Examiner

ZACHARY C. HOWARD

Art Unit

1646

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29, 30, 36-40, 46-49 and 52-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29, 30, 36-40, 46-49, 52-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notices of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Application, Amendments and/or Claims

On 8/3/09, Applicants filed a response to the previous Office Action with includes a listing of claims which does not include any claim amendments (each pending claim listed as "Previously Presented"). This claim listing has been entered.

Claims 29, 30, 36-40, 46-49 and 52-54 are pending in the application.

Maintained Objections and/or Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 29, 30, 36-40, 46-49 and 52-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Motoyama et al (18 February 1998. Nat Genet. 18(2): 104-6; cited previously) in view of Tso et al (U.S. Patent No. 5,932,448, published 8/3/88, and filed 11/29/1991; cited previously). This rejection was set forth previously and maintained at pg 2-6 of the 3/2/09 Office Action.

Applicants' arguments (8/3/09; pg 4-5) as they pertain to the rejection have been fully considered but are not deemed to be persuasive for the following reasons.

In the response, Applicants state that the rejection is based on a "hypothetical combination of Motoyama and Tso stating that one of skill in the art would be motivated to make anti-patched-2 antibodies against the polypeptide disclosed in Motoyama using the techniques disclosed in Tso and that such antibodies "would inherently bind specifically to the human patched-2 polypeptide of SEQ ID NO: 2, absent evidence to the contrary"". Applicants point to MPEP 2112 as indicating that a *prima facie* case of inherency requires a "basis of fact and/or technical reasoning to reasonably support the determination that the alleged inherent characteristic necessarily flows from the

teachings of the applied prior art"; that "mere possibilities or probabilities are not enough to establish inherency" and "the result must flow inevitably and always". Applicants argue that the instant rejection fails to "satisfy the burden of providing a sufficient basis of fact or technical reasoning to show that a hypothetical monoclonal antibody produced against the mouse protein that is only "89.3% similar" to the human patched-2 polypeptide would inevitably and always bind to the human patched-2 protein".

Applicants' arguments have been fully considered but are not persuasive for the following reasons. All 103(a) rejections are "hypothetical" because they are based on obviousness rather than anticipation. Applicants' characterization of MPEP 2112 is not disputed. The rejection set forth previously provided technical reasoning to reasonably support the determination that anti-patched antibodies generated as taught by Tso et al against the mouse patched-2 protein taught by Motoyama would include antibodies that inherently bind to the human patched-2 protein of SEQ ID NO: 2. As set forth previously, the pool of antibodies generated against the mouse patched-2 polypeptide taught by Motoyama et al would inherently include antibodies that also bind to instant SEQ ID NO: 2 (human patched-2 polypeptide). The relevant art provides evidence that "the size of an epitope is approximately equivalent to 5-7 amino acids" (see pg 40 of Benjamini et al, 1991. Immunology: A Short Course, 2nd edition; cited previously; included here solely to support inherency). An alignment between the mouse patched-2 polypeptide taught by Motoyama et al and instant SEQ ID NO: 2 reveals numerous regions of 100% identity that comprise 5 or more amino acids (see the alignment of instant SEQ ID NO: 2 ("Qy") and the mouse patched-2 polypeptide taught by Motoyama et al ("Db") provided in the previous Office Action at pages 4-5). For example, residues 82-119 share 100% identity, providing a stretch of 28 amino acids that are identical between the two proteins. Each region of exact identity of 5 or greater amino acids therefore contain identical epitopes that would inherently generate antibodies that would bind to either polypeptide. The term "specifically binds" is not defined in the specification as excluding antibodies that bind to the same epitope in other polypeptides (e.g., mouse patched-2); and therefore broadly encompasses antibodies that bind to the same epitope in two different sequences. Therefore, the set of antibodies generated against

the mouse patched-2 polypeptide taught by Motoyama et al would inherently include antibodies that specifically bind to an epitope also found within the human polypeptide of SEQ ID NO: 2.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C. Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number: 09/990,046
Art Unit: 1646

Page 5

/Z. C. H./
Examiner, Art Unit 1646

/Bridget E Bunner/
Primary Examiner, Art Unit 1647